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No. 98-1768

In the Supreme Court of the United States

THE BUCKMAN COMPANY,

Petitioner,

v.

PLAINTIFFS' LEGAL COMMITTEE,

Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Third Circuit

BRIEF *AMICUS CURIAE* OF THE MEDICAL DEVICE MANUFACTURERS ASSOCIATION IN SUPPORT OF PETITIONER

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QUESTION PRESENTED

Whether federal law preempts state-law tort claims alleging fraud on the Food and Drug Administration during the regulatory process for marketing clearance applicable to certain medical devices.

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INTEREST OF *AMICUS CURIAE*

The Medical Device Manufacturers Association ("MDMA") is a national trade association based in Washington, D.C. that represents nearly 130 independent manufacturers of medical devices, diagnostic products and health care information systems. MDMA seeks to improve the quality of patient care by encouraging the development of new medical technology and fostering the availability of beneficial innovative products. To achieve these goals, MDMA represents its members' collective interests before the United States Congress, the Food and Drug Administration ("FDA"), other federal agencies, and courts that develop, implement or interpret policies that affect the medical device industry. MDMA has a significant interest in this case because it raises important liability issues with broad implications for the entire medical device industry.[1]

SUMMARY OF ARGUMENT

The Medical Device Amendments of 1976 expressly and impliedly preempt the state law fraud claims asserted by Plaintiffs. The claims are expressly preempted under 21 U.S.C. § 360k(a), because they would establish state law

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[1] Pursuant to Supreme Court Rule 37.6, *amicus curiae* affirms that no counsel for either party authored this brief in whole or in part, and no person or entity other than *amicus curiae* and its members made a monetary contribution to the preparation or submission of the brief.

Pursuant to Supreme Court Rule 37.2, written consent to the filing of this brief has been obtained from counsel for both parties, and the documents reflecting consent have been filed with the Clerk's office.

requirements "different from, or in addition to," applicable federal requirements. The relevant federal requirements require parties seeking premarket clearance to submit information to the FDA to demonstrate that the device under review is substantially equivalent to a predicate device that was in commercial distribution before the Medical Device Amendments were enacted. This information includes the device's proposed labeling describing its "intended use."

"Intended use" is a term of art that refers to the functional capabilities of the device, or in the words of the FDA, "what the device does." The purpose of the federal submission requirement is solely to allow the FDA to determine whether the device's functional capabilities as described in the proposed labeling are the same as those set forth in the labeling of the predicate device. Significantly, the description of "intended use" is *not* a representation of the manufacturer's subjective intent about what the *actual* uses of the device by medical professionals may be following clearance. It is well settled that once the FDA has cleared a medical device for one use, medical professionals may legally employ the device for other, "off-label," uses. The required statement of "intended use" says nothing about the submitter's subjective intent with respect to such off-label uses.

Plaintiffs' claims would establish state law disclosure requirements that are different from, and in addition to, these federal submission requirements. If plaintiffs' claims were allowed to proceed, they would require parties that seek premarket clearance to disclose their subjective intent with regard to possible off-label uses once clearance is obtained. Because federal law imposes no such requirement, Plaintiffs' claims are preempted under section 360k(a).

The Court also should hold that Plaintiffs' claims are impliedly preempted, because they would frustrate the

Congressional purpose underlying the Medical Device Amendments. If such claims were not barred by preemption, they would interfere with the FDA's statutory responsibility to make critical new medical devices available promptly for patient treatment. Such claims certainly would entangle agency personnel in tort litigation between private parties. Involving FDA officials in such tort litigation would divert them from their important product clearance functions, thereby delaying the availability of critical medical devices.

Fraud on the agency claims also would create incentives to burden the FDA with additional submissions of information. If fraud on the agency claims were preserved from preemption, manufacturers would attempt to protect themselves against fraud liability by submitting to the agency all information that is even arguably relevant to product clearance, to guard against later allegations that it made material omissions in communications with the agency. The resulting burden on the agency to review the information submitted would further delay product clearances, thereby undermining the congressional purpose.

Preserving fraud on the agency claims also would interfere with the FDA's authority to remedy fraud in its premarket clearance processes. The FDA has extensive authority to remedy such fraud, and the proper role of a private party is to refer alleged frauds for investigation by the agency, not to pursue independent remedies for fraud under state law. The Supremacy Clause does not allow private parties to invoke state law to meddle with this federal scheme, and as a result Plaintiffs' claims are impliedly preempted.

ARGUMENT

The state law claims at issue in this case assert that Petitioner, The Buckman Company, is liable for fraudulently misrepresenting the intended use of orthopedic bone screws in premarket clearance notifications that it filed with the FDA on behalf of AcroMed Corporation. Perhaps because Buckman is not itself a medical device manufacturer, and instead is a regulatory consultant with no control over its clients' manufacturing operations, the claims do not allege that there were any product defects in the bone screws. The claims instead assert simply that the bone screws never would have been on the market but for the alleged misrepresentations in the premarket clearance notifications. Through these claims, Plaintiffs seek to second-guess the FDA's actions under federal law in reviewing AcroMed's notifications and clearing the bone screws for marketing.

The Supremacy Clause does not permit Plaintiffs to invoke state law to meddle in this manner with the federal regulatory scheme. Plaintiffs' claims should be dismissed, because Congress has both expressly and impliedly preempted them.

I. THE MEDICAL DEVICE AMENDMENTS EXPRESSLY PREEMPT PLAINTIFFS' STATE LAW CLAIMS FOR FRAUD ON THE FDA

A. The Medical Device Amendments Expressly Preempt Fraud Claims That Would Impose State Law Requirements Different From, or in Addition to, Federal Requirements

Congress's intent to preempt state law "may be 'explicitly stated in the [federal] statute's language or implicitly contained in its structure and purpose.' " *Cipollone v. Liggett Group*, 505 U.S. 504, 516 (1992) (quoting *Jones v. Rath*

Packing Co., 430 U.S. 519, 525 (1977)). The Medical Device Amendments of 1976 ("MDA") contain the following express preemption provision, which Congress intended to be a "general prohibition on non-Federal regulation" (H.R. Rep. No. 94-853, at 45 (1976):

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a). Plaintiffs' claims would impose state law requirements "different from, or in addition to" federal requirements governing disclosures in premarket clearance notifications, for the reasons set forth below.

B. Federal Premarket Clearance Regulations Requiring Submission of Proposed Labeling Describing a Device's "Intended Use" Do Not Require Disclosing the Applicant's Subjective Intent Regarding Possible Off-Label Uses

1. The Federal Premarket Clearance Regulations at Issue Require the FDA to Classify the Device Under Review

The FDA authorized the marketing of the orthopedic bone screws at issue in this case through the Section 510(k) premarket clearance process. This process is established by, and named after, Section 510(k) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 360(k), under

which prospective new manufacturers present information about the device to the FDA to obtain marketing authorization. The FDA uses this information to determine whether the device under review is "substantially equivalent" to a predicate "preamendment" device marketed before the MDA were adopted in 1976. The FDA authorizes marketing if the devices are substantially equivalent and denies clearance if they are not. *See* 21 C.F.R. § 807.100.

When it determines that a device is substantially equivalent, the FDA assigns it to the same regulatory classification as its preamendment predicate. The FDA has classified preamendment devices into one of three regulatory categories based upon questions they raise about safety and effectiveness. Class I devices are those presenting the least risk, and are regulated to provide reasonable assurance of safety and effectiveness through general controls. Class II devices are those requiring additional special controls, such as performance standards and specific guidelines, to provide such assurance. Finally, Class III devices are those presenting risks requiring full premarket clearance to provide such assurance. 21 U.S.C. § 360c. By determining that the bone screws at issue in this case were entitled to Section 510(k) clearance, the FDA assigned them to the same classification applicable to their preamendment predicates.

One of the purposes of this classification procedure and substantial equivalence review is to give manufacturers of postamendment devices "the freedom to compete, to a limited degree, with and on the same terms as manufacturers of medical devices that existed prior to 1976." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 494 (1996). Such "preamendment" devices are exempt from premarket clearance requirements (unless they have been classified in Class III and the FDA promulgates a regulation requiring otherwise). *See* 21 U.S.C. § 360e(a)(1). The Section 510(k) process ensures that

manufacturers of such devices do not "monopoliz[e] the market" to the detriment of manufacturers of substantially equivalent postamendment devices. *See Medtronic*, 518 U.S. at 478.

2. The FDA's Substantial Equivalence Review Includes an Evaluation of the Device's Functional Capability, Termed "Intended Use," Described in Proposed Labeling

In order to obtain Section 510(k) clearance, a manufacturer must demonstrate (among other things) that its device can perform the same therapeutic function as a specific preamendment device. The regulatory term of art for this therapeutic function is "intended use." FDA accordingly employs the term intended use to designate "what the device does" and to "refer[] to the functional capability of the device." U.S. Dept. of Health and Human Services, *Medical Device Labeling – Suggested Format and Content* (Apr. 25, 1997) at 5.

The FDA determines whether the functional capabilities of the devices are the same by reviewing the device description and by comparing statements in the labeling of the preamendment device with statements in the proposed labeling of the device under review. *Guidance on the Center for Devices and Radiological Health's Premarket Notification Review Program* (June 30, 1986) (K86-3) at 5. The labeling need not be identical. *Id.* The agency makes the comparison by examining (among other things) labeling statements regarding "physiological purpose, . . . condition or disease to be treated or diagnosed, professional or lay use, parts of the body or types of tissue involved, [and] frequency of use." *Id.* If this analysis establishes that the device under review does not have the same functional capability as a preamendment device, it obviously cannot be substantially equivalent. Therefore FDA's regulatory practice in 1986,

when it cleared the devices at issue for marketing, was to deny premarket clearance if this review of labeling, together with the physical device description, indicated that the device under review had a different functional capability (termed intended use) than the predicate preamendment device. *Id.* at 4-5, 7. Congress codified this practice in 1990 and 1997, when it enacted legislation specifying that the agency's determination "of the intended use of a device shall be based upon the proposed labeling" and that a device must have "the same intended use as the predicate device" to be substantially equivalent. 21 U.S.C. § 360c(i)(1)(E)(i), (1)(A) (Supp. IV 1998).

3. Required Statements of Intended Use Are Statements Regarding the Functional Capabilities of the Device Under Review And are Not Representations of Subjective Intent Regarding the Actual Uses the Device Will Perform Following Premarket Clearance

In this case, the preemptive federal requirements "applicable . . . to the device" (21 U.S.C. § 360k(a)(1)) are those that govern submission of information regarding a device's "intended use" to the FDA in connection with a Section 510(k) premarket clearance notification. The version of the FDA's regulations in effect during the relevant time period (like the current version) required submitting "[p]roposed . . . labeling . . . sufficient to describe the device [under review and] its intended use . . ." 21 C.F.R. § 807.87(e) (1986). The purpose of this submission requirement is solely to allow the FDA to determine whether the new device's functional *capabilities* as described in the proposed labeling are the same as those set forth in the labeling of a preamendment device. The description of intended use in a Section 510(k) notification therefore is *not a representation of the manufacturer's subjective intent*

about what actual uses of the device may occur following clearance.[2]

Other provisions of the FDCA, FDA regulations and agency pronouncements all confirm this understanding of "intended use." *First*, the FDCA indicates that the FDA's review of Section 510(k) statements regarding intended use is exclusively for purposes of a labeling comparison between the device under review and its preamendment predicate — and is not an inquiry that extends into issues other than substantial equivalence. 21 U.S.C. § 360c(i) requires that the FDA's determination of intended use in its substantial equivalence analysis "shall be based upon the proposed labeling." The legislative history of the same provision confirms that this determination from the labeling "will be controlling," and that the relevant consideration is "whether or not the proposed labeling of the newer device is compatible with the labeling of the predicate device."

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2 At the time the bone screws at issue were cleared for marketing in 1986, the FDA was well aware that medical professionals may legally use devices cleared through the Section 510(k) process for uses that are not described in the labeling. *See, e.g.*, James M. Beck & Elizabeth D. Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 Food & Drug L.J. 71 (1993) at 76-80. The agency has recognized that such "off-label" uses are legitimate and important for the public health, because cutting-edge therapies are frequently developed through "off-label" uses of devices cleared by the FDA for a different use. *See, e.g.*, Pet. App. at 28a n.1. Judge Cowan's dissent below properly explained that "[t]he FDA and the medical community have long recognized the importance of doctors' off-label uses of medical products (uses not indicated on the label or approved by the FDA)." Pet. App. at 28a.

S. Rep. No. 105-43, at 27 (1997).[3] Accordingly, the subjective intent of the applicant regarding possible uses not listed in the proposed labeling is simply not relevant to the Section 510(k) submission or its review by the FDA.

Second, by confirming that statements in proposed labeling are the basis for the agency's comparison of intended use between the device under review and its preamendment predicate, Congress necessarily also has indicated that information about other possible uses of either device (not listed in their labeling) is *not* relevant to substantial equivalence. The legislative history of 21 U.S.C. § 360c(i) expressly confirms that "[n]o considerations outside of the proposed labeling for the Section 510(k) device should bear on the question" of substantial equivalence. S. Rep. No. 105-43 at 27. Because off-label uses are not relevant to the substantial equivalence determination, and the sole purpose of a Section 510(k) notification is to demonstrate substantial equivalence, an applicant for Section 510(k) clearance has no obligation to notify the FDA about possible off-label uses. To conclude otherwise would place a duty on the manufacturer of a new device to disclose every possible off-label use of which it is aware. The FDA regulations

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[3] Although enacted in 1997, this statement of congressional intent simply codifies agency practice extending back at least as early as 1986, when the FDA granted premarket clearance for the orthopedic bone screws at issue. *See Determination of Intended Use for 510(k) Devices – Guidance for Industry and CDRH Staff* (Jan. 30, 1998) at 1 (statutory requirement "not different from the manner in which 510(k)s have traditionally been reviewed"); *Guidance on the Center for Devices and Radiological Health's Premarket Notification Review Program* at 10 n.3 (intended use ordinarily determined by reference to labeling or promotional claims).

specifying the contents of a Section 510(k) notification simply do not require such a disclosure. *See* 21 C.F.R. § 807.87 (1986).[4]

Third, FDA's regulations confirm that a statement of intended use is not a statement of subjective intent. To the contrary, "the words *intended use[]* . . . refer to the objective intent of the persons legally responsible for the labeling of the devices." 21 C.F.R. § 801.4. "Intended use" is a term of art that does not encompass the subjective intent of the applicant for premarket clearance.

Finally, the submission of proposed labeling containing a statement of intended use is not a representation that the device will ever *actually* be manufactured or sold for *any* purpose. The FDA has made clear that there is "no requirement that an actual prototype of a device must be manufactured" in order to receive premarket clearance. *Premarket Notification: 510(k) Regulatory Requirements for Medical Devices* (Feb. 1986) at 2. Furthermore, *amicus curiae* is familiar with a number of instances in which the

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[4] 1997 amendments to the Federal Food, Drug, and Cosmetic Act do require that in order to obtain Section 510(k) clearance, a 510(k) notification submitter may be required to modify its label to describe certain off-label uses that "could cause harm" and to specify limitations on such uses. 21 U.S.C. § 360c(i)(E). This provision does not impose any requirement to *disclose* possible off-label uses in the Section 510(k) notification in the first instance; indeed, the statute assumes that such uses are "not identified in the proposed labeling" submitted with the device. *Id.* The provision instead simply allows the agency, if it has information regarding potentially harmful off-label uses from *any* source, to require labeling warnings as a condition of premarket clearance. And in any event, the provision does not apply to the clearances at issue in this case, which were obtained in 1986.

agency has cleared a device for marketing as substantially equivalent yet the manufacturer has decided not to manufacture or sell the device in the marketplace. The Section 510(k) process only determines whether marketing is *permissible* because of similarities in functional capability between the device under review and the predicate device. The process does not seek to determine whether marketing will in fact occur, and if so, what therapeutic use will actually be made of the device.

C. Plaintiffs' Claims Would Impose State Law Requirements Different From, or in Addition to, Federal Requirements by Requiring a Premarket Clearance Applicant to Disclose its Subjective Intent Regarding Possible Off-Label Uses

Plaintiffs' claims are preempted, because they would impose state law requirements "different from, or in addition to," the federal requirements explained above requiring submission of proposed labeling describing intended use. Although the federal requirements do not require disclosure of the applicant's subjective intent regarding off-label uses for the reasons described above, the premise of Plaintiffs' claims is that state law does impose a duty to make such disclosures. A majority of this Court confirmed in *Medtronic* that state tort law duties are state "requirements" within the meaning of the MDA express preemption provision. *Medtronic*, 518 U.S. at 503-04 (Opinion of Breyer, J.), 509 (Opinion of O'Connor, J.); *see also Geier v. American Honda Motor Co.*, 120 S. Ct. 1913, 1918, 1934 (2000) (*Medtronic* recognized that reference to state "requirement" in express preemption provision may include common law duties). Because they would require disclosures to the FDA that applicable federal requirements do not, these state requirements are obviously "different from, or in addition

to," the federal requirements. Accordingly, the Court should hold that Plaintiffs' claims are expressly preempted.

II. THE MEDICAL DEVICE AMENDMENTS IMPLIEDLY PREEMPT PLAINTIFFS' STATE LAW CLAIMS FOR FRAUD ON THE FDA

A plurality of this Court expressly recognized in *Medtronic* that in a future case, it might conclude that tort claims involving a medical device were "preempted under conflict preemption analysis." *Medtronic*, 518 U.S. at 503. This is such a case. Under the doctrine of implied "conflict" preemption, state law is invalid if it "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941). This Court has recognized that state law presents such an obstacle if it "interferes with the methods by which the federal statute was designed to reach" its goals. *International Paper Co. v. Ouellette*, 479 U.S. 481, 494 (1987). Applying these standards, the Court should hold that the MDA impliedly preempt Plaintiffs' state law claims.

A. Preserving Fraud on the Agency Claims Would Interfere With the FDA's Statutory Responsibility to Bring Needed Therapies to Patients As Quickly As Possible

Preserving fraud on the agency claims from preemption would interfere with the FDA's statutory responsibility to "promote the public health by . . . taking appropriate action on the marketing of regulated products in a timely manner." 21 U.S.C. § 393(b)(1). Because federal law prohibits manufacturers from distributing most new medical devices without prior clearance from the FDA (*see, e.g.*, 21 U.S.C. §§ 360e, 360(k) (1994 & Supp. 1998)), delays in premarket clearance profoundly affect patients' health by postponing

their access to innovative device therapies. The FDA has recognized the importance of streamlining its premarket clearance processes to "bring needed therapies to patients as quickly as possible." *Hearing Before the Subcomm. On Oversight & Investigations of the House Comm. On Commerce* (Sept. 23, 1997) (statement of Michael A. Friedman, Lead Deputy Commissioner, FDA). Yet fraud on the agency claims such as those at issue in this case would hamper the FDA's ability to meet its statutory mandate to provide prompt premarket clearance for devices.

1. Fraud on the Agency Claims Would Delay Premarket Clearance by Entangling FDA Personnel in Litigation Between Private Parties

Until the Third Circuit's decision in this case, most lower courts had held (both before and after *Medtronic)* that the MDA preempt claims for fraud on the FDA. *See* Pet. for Cert. at 11-15. If such claims were instead preserved from preemption, as the Third Circuit held, they would increasingly cause delays in premarket clearance by entangling FDA personnel in litigation between private parties. The Solicitor General's *amicus curiae* brief in support of the Petition for Certiorari properly concluded that such litigation would "pose a significant potential for diverting an agency's resources and for distorting its internal decisionmaking processes." Br. for the United States as Amicus Curiae at 17.

Fraud claims such as those at issue here assert that misrepresentations were made to FDA officials responsible for premarket clearance decisions, who in turn authorized marketing of a medical device in reliance on the misrepresentations. These officials obviously would be critical witnesses to the alleged fraud in a tort suit, because their personal knowledge typically would determine whether

a misrepresentation occurred, and if so, whether it affected premarket clearance of a medical device. Given their unique knowledge of the facts at issue in a fraud on the agency claim, FDA officials would be important witnesses for both the plaintiff and defendant. Indeed, in the present case, Plaintiffs claim that Petitioner misled agency officials, yet Petitioner contends that its course of action (now alleged to be fraudulent) was *suggested* by the FDA. *See* Pet. for Cert. at 17 n.8. For both parties, the witnesses who could provide the best evidence to resolve factual disputes like this one would be the FDA officials who reviewed and acted on the manufacturer's premarket clearance submissions.

Because they would be such important witnesses in fraud on the agency claims, FDA officials would be vulnerable to entanglement in tort litigation. Although the FDA, like other agencies, has promulgated "housekeeping" regulations that purport to restrict its obligation to respond to third party subpoenas issued in litigation between private parties, *see* 21 C.F.R. § 20.1, those regulations do not guarantee the agency any protection against involvement in tort suits. The regulations themselves authorize testimony if the public interest so requires. *See id.; In re U.S. Bioscience Sec. Litig.*, 150 F.R.D. 80 (E.D. Pa. 1993) (enforcing subpoenas for deposition testimony of FDA employees in private securities litigation).

Furthermore, at least since the Ninth Circuit's decision in *Exxon Shipping Co. v. Department of Interior*, 34 F.3d 774 (9th Cir. 1994), the lower courts increasingly have cast substantial doubt on the validity of such housekeeping regulations. In *Exxon*, the Ninth Circuit held that five federal agency heads could not rely on their agencies' housekeeping regulations to prevent subordinate employees from testifying pursuant to third party deposition subpoenas. The Ninth Circuit rejected the argument that this Court's decision in

United States ex rel. Touhy v. Ragen, 340 U.S. 462 (1951) permitted federal agencies to refuse to allow their employees to respond to valid third-party subpoenas by invoking such regulations. *Exxon*, 34 F.3d at 778.[5] The court concluded that just like any other witness, a federal employee witness is required to comply with a federal court subpoena under the standards set forth in Fed. R. Civ. P. 45. *Id.* at 779. Following *Exxon*, numerous other lower courts also have held that government agencies — including the FDA — may not rely on housekeeping regulations to withhold information sought through third-party subpoenas. *See, e.g., Houston Business Journal, Inc. v. Office of Comptroller of Currency*, 86 F.3d 1208, 1212 (D.C. Cir. 1996) (housekeeping regulations do not authorize withholding subpoenaed documents in conflict with Fed. R. Civ. P. 45); *Connaught Labs., Inc. v. SmithKline Beecham*, 7 F. Supp.2d 477 (D. Del. 1998) (rejecting restrictions of FDA housekeeping regulations and enforcing subpoenas for testimony of FDA employees in patent litigation between private parties).

Once subpoenas were issued in a fraud case, the drain on the time and resources of agency personnel required for

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5 In *Touhy*, the Court held that an FBI official could not be held in contempt for obeying an order by his superior — the Attorney General — to refuse production of documents pursuant to a third-party subpoena. *Touhy* therefore addressed the question whether the Attorney General, as head of an agency, had authority to "centraliz[e] determination as to whether subpoenas *duces tecum* will be willingly obeyed or challenged" by implementing housekeeping regulations that "withdraw from his subordinates the power to release department papers." 340 U.S. at 467-68. The Court expressly refused to reach the question whether the agency itself had a "privilege against disclosure" (*id.* at 468, 469 & n.9) allowing it to "refuse to produce government papers." *Id.* at 469.

subpoena responses would be substantial. The scope of relevant testimony and documents potentially would be quite broad, because every communication between the manufacturer and the FDA regarding premarket clearance could be a source of evidence in a case alleging fraud on the agency, and such communications are numerous; the FDA's review of premarket clearance submissions is a collaborative process between the manufacturer and the agency, involving frequent dialog over a period of months or even years.

For example, the agency has long encouraged early meetings between manufacturers and FDA officials to exchange information about a new device even before the FDA has approved clinical studies that may be required for eventual premarket clearance. *See Guidance on IDE Policies and Procedures* at 1 (Jan. 20, 1998) <http://www.fda.gov/cdrh>; *Goals and Initiatives for the IDE Programs* IDE Mem. #D95-1, at 2 (July 12, 1995) <http://www.fda.gov/cdrh/d951.htm1>. In 1997, Congress endorsed a similar interactive process by amending the FDCA to require the FDA, upon written request, to meet with the applicant for a premarket approval application ("PMA") within 100 days after the PMA is filed. 21 U.S.C. § 360e(d)(3). The agency does not limit itself to this required meeting and goes "beyond the [statutory] requirements by encouraging 'exploratory' meetings very early in the premarket review process and continued interactions throughout the review process." *FY 2000 Budget Request* at 1 <http://www.fda.gov/oc/oms/ofm/budget/devnctrtab.htm>. The FDA has agreed "to communicate with each firm at least every four weeks subsequent to the 100-day meeting." *FDA/CDRH Annual Report FY 1998* at 1 <http://www.fda.gov/cdrh/index.html>.

A fraud on the agency claim would potentially require FDA personnel to respond to discovery concerning each of

these communications, thereby diverting substantial resources from review of premarket clearance notifications. Distracting agency officials from their critical device review functions would undermine the congressional purpose by retarding the clearance of promising new therapies that could substantially improve the public health.

2. Fraud on the Agency Claims Would Delay Premarket Clearance by Creating Incentives to Burden the FDA With Needless Submissions of Information

If fraud on the agency claims were preserved from preemption, they also would delay premarket clearance by creating incentives to burden the FDA with additional submissions of information. Manufacturers would attempt to protect themselves against fraud liability by submitting to the agency all information that is even arguably relevant to product clearance, to guard against later allegations that there were material omissions in communications with the agency. *See* Pet. for Cert. at 18.

These additional information submissions would be unnecessary. For example, in the present case, the agency had no need for additional information to determine whether it had been defrauded. Only three months passed between the premarket clearance notification that plaintiffs allege revealed defendants' true subjective intended use (spinal surgery) and the notification that plaintiffs allege fraudulently misrepresented the intended use as for the long bones in the arms and legs. Pet. App. at 5a. The FDA officials responsible for reviewing these applications manifestly had full notice that the intended use had been changed — and according to the petition had in fact *encouraged* the change (Pet. for Cert. at 17 n.8) — at a time when it was well known at the agency that "[i]n practice, surgeons often use orthopedic screws which FDA has cleared for other

purposes" in spinal surgery instead. *See FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 Food & Drug L.J. at 77 (citing FDA, Update on Pedicle Screws).

Though needless, the additional information submissions would have a deleterious effect on the FDA's product clearance work. Once the information was submitted, it would need to be reviewed by FDA personnel who already have limited budgetary resources. Furthermore, in recent years, the number of FDA employees in the Office of Device Evaluation ("ODE") — the office responsible for reviewing premarket clearance applications — has steadily fallen. 1996 ODE Annual Report at 1; 1997 ODE Annual Report at 1; 1998 ODE Annual Report at 2, *supra*; 1999 ODE Annual Report at 2. Increasing the amount of information for these officials to review would increase product clearance times and delay the marketing of innovative therapies for patient use.

The tort system would create this effect after the FDA, both on its own initiative and with congressional urging, has made great strides to reduce clearance times by *diminishing* the information required to be submitted for agency review. *See, e.g.*, 21 U.S.C. § 360c(a)(3)(C) (requiring the FDA to consider "whether the extent of data that otherwise would be required for approval of the application with respect to effectiveness can be reduced through reliance on postmarket controls"). For example, the FDA now requires submission of less information for Section 510(k) notifications regarding low risk devices (because clearance decisions are based primarily on descriptive information and a labeling review) than it does for high risk devices (for which clearance decisions rely on performance data). *The New 510(k) Paradigm* at 3 (Mar. 20, 1998) <http://www.fda.gov/cdrh/ode/parad510.html>. The agency also requires more

information in a Section 510(k) notification seeking initial clearance for a device than it does for a notification seeking clearance for a change in a previously marketed device. *FY 2000 Budget Request* at 2, *supra*. To reduce submission requirements regarding Section 510(k) notifications further, the FDA also permits manufacturers to certify compliance with certain material and performance standards in lieu of submitting information demonstrating compliance. *Id.* Because it has streamlined the submission process, the FDA review time for Section 510(k) notifications during fiscal year 1998 was only *half* what it was only four years earlier. *FDA/CDRH Annual Report FY 1998* at 7, supra.

Fraud claims of the type at issue in this case would undermine this important progress, interfering with the statutory purpose of accelerating clearance of critical new devices. In so doing, such claims would "stand[] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" (*Hines*, 312 U.S. at 67) — a circumstance that this Court has long viewed as giving rise to implied preemption of state law.

B. Preserving Fraud on the Agency Claims Would Interfere With the FDA's Authority to Remedy Fraud in its Premarket Clearance Processes

Preserving fraud on the agency claims also would frustrate the congressional purpose by interfering with the FDA's authority under federal law to remedy fraud in its premarket clearance processes. Plaintiffs allege that the agency was defrauded, even though the agency — with all relevant facts before it — does not appear to agree. The Supremacy Clause does not allow Plaintiffs to invoke state law to meddle with the FDA's unique responsibility to remedy fraud in its premarket clearance processes.

Under federal law, the agency has extensive tools at its disposal to root out and punish fraud in its premarket clearance processes. The agency proceeds under its "fraud policy" to investigate "acts such as submitting fraudulent applications, making untrue statements of material facts, or giving or promising bribes or illegal gratuities [that] may call into question the integrity of some or all of the applicant's submissions to the agency." 56 Fed. Reg. 46,191, 46,199 (1991). If fraud is uncovered, the FDA exercises its authority "under applicable statutes and regulations, to refuse to approve the application (in the case of a pending application) or to proceed to withdraw approval (in the case of an approved application)." *Id.* at 46,200. The FDA also refers fraud cases for criminal prosecution by the Department of Justice, because violation of the FDCA's prohibitions with "intent to defraud or mislead" is a felony. 21 U.S.C. §§ 331, 333(a)(2); *see also United States v. Cambra*, 933 F.2d 752, 755 (9th Cir. 1991) (FDCA felony provision prohibits fraud on government enforcement agencies). The federal Sentencing Guidelines include a sentencing enhancement for FDCA felony violations involving fraud if the government obtains a conviction. U.S.S.G. §§ 2N2.1(b)(1); 2F1.1.

In this regulatory scheme, with its "general prohibition on non-Federal regulation" (H.R. Rep. No. 94-853 at 45), the proper role of a private party is to *refer* alleged frauds to the agency for investigation, not to act as a private attorney general pursuing independent remedies under state law. For example, the FDA's "Citizens Petition" process allows any person to request the agency to withdraw a product clearance obtained through fraud. *See* 21 C.F.R. § 10.30. Plaintiffs are well aware of this process, having filed a Citizens Petition (with 1,000 pages of supporting material) alleging fraud on the agency and seeking withdrawal of one manufacturer's bone screw product clearance. Citizens Petition, FDA

Docket No. 98P-0623 (July 24, 1998). In addition, private parties may bring alleged frauds to the attention of the agency through contacts with FDA enforcement personnel. The Supremacy Clause, however, precludes such parties from employing state law to pursue their own private theories of fraud, thereby undermining the enforcement scheme intended by Congress.

CONCLUSION

For the reasons set forth above, the judgment of the court of appeals should be reversed.

Respectfully submitted,

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